IN THE UNITED STATES DISTRICT COURT DISTRICT OF SOUTH CAROLINA BEAUFORT DIVISION

United States of America, et al.,)	Civil Action No. 9:14-cv-00230-RMG (Consolidated with 9:11-cv-1593-RMG and
Plaintiffs,)	9:15-cv-2458-RMG)
)	
ex rel. Scarlett Lutz, et al.,)	
)	ORDER and OPINION
Plaintiffs-Relators,)	
)	
v.)	
)	
Berkeley Heartlab, Inc., et al.,)	
)	
Defendants.)	
)	

This matter is before the Court on the BlueWave Defendants' Motion for Clarification (Dkt. No. 763) of this Court's prior Order on the Government's Motions in Limine (Dkt. No. 736). The Court has reconsidered and clarified its prior Order as set forth below.

I. Background

In its Motion in Limine, the Government asked the Court to exclude testimony from physician witnesses not disclosed as expert witnesses about the medical necessity of laboratory tests. (Dkt. No. 588.) The Court ruled as follows on that issue:

Under Rule 26(a)(2)B) of the Federal Rules of Civil Procedure and this Court's Scheduling Order, Defendants were required to identify and disclose all experts by February 6, 2017, including the subject matter on which the expert was expected to testify and a summary of the expert's opinions. The BlueWave Defendants have disclosed and provided an expert report from Dr. Robert Fishberg on the issue of medical necessity of laboratory tests. The Government did not move to exclude Dr. Fishberg. Defendants disclosed no other experts to testify on the issue of medical necessity. Later, in their pre-trial disclosures, Defendants identified several physicians they intend to call at trial, including Dr. Joseph McConnell, Dr. Tauqueer Alam, Dr. Joe Hollins, Dr. Rex Butler, Dr. John Eberly, Dr. Samual Fillingane, and Dr. Szilard Voros. (Dkt. Nos. 563 at 3-4; 583 at 4.) The BlueWave Defendants also stated that they intended to present the

deposition testimony of Dr. Tara Dall, HDL's former Chief Medical Officer. Defendants claim that these physicians may testify as lay witnesses because they are treating physicians.

To the extent that these physicians would testify about the medical necessity of laboratory tests either in routine clinical practice or for a particular patient, that testimony is based on "scientific, technical, or other specialized knowledge" so falls in the category of expert testimony. FRE 701, 702. The testimony of treating physicians that involves "diagnosis, prognosis, and future medical care is opinion testimony that falls under Rule 26(a)(2)(A)'s expert disclosure requirement." See, e.g., Stogsdill v. S.C. Dep't of Health & Human Servs., Civ. A. No. 3:12-0007-JFA, 2017 WL 3142497, *15 (D.S.C. July 25, 2017) (appeal pending); Ingram v. ABC Supply Co., Civ. A. No. 3:08–1748–JFA, 2010 WL 233859, *2 (D.S.C. Jan. 14, 2010). If it is true, as Defendants claim, that the physicians' testimony is "a far cry from utilizing medical training and expertise to evaluate an individual patient's symptoms, course of treatment, and medical history, offer a diagnosis or prognosis..." (Dkt. No. 642 at 15), then the physicians' testimony is not probative of any material issue in this case.

For these reasons, any probative testimony these physicians would provide falls under the disclosure requirements of Rule 26. Defendants did not comply with Rule 26, and their argument that their failure to do so is justified or harmless fails. Defendants have offered no justification for their failure to identify these physicians as expert witnesses earlier, and the Government would be prejudiced by the introduction of expert testimony for which it had no opportunity to procure a rebuttal report. While the Government did have the opportunity to depose some of these physician witnesses, it did not at the time of those depositions have notice of the facts and opinions those physicians would introduce at trial if they testified as expert witnesses. Because Defendants failed to comply with Rule 26 and their failure was neither justified nor harmless, they may not introduce the testimony of these physician witnesses about the medical necessity of laboratory tests. Defendants will have the opportunity to introduce the expert testimony of their [expert] Robert Fishberg about the medical necessity of laboratory tests, so the Court is not concerned that its decision to exclude certain testimony from these physicians is unfairly prejudicial. For the reasons set forth above, the Government's motion to exclude the physician testimony discussed in the parties' briefs is granted.

(Dkt. No. 736 at 14-16.)

Defendants have asked the Court to clarify or reconsider this portion of its prior Order to allow them to introduce testimony from treating physicians regarding their personal knowledge of essential facts in this case and their reasons for making diagnosis and treatment decisions for particular patients. Defendants anticipate that the physicians' testimony would cover the following issues:

(1) background information on their medical practices, patient populations and their reasons for ordering lab tests; (2) BlueWave's sales and marketing practices; (3) process and handling (P&H) agreements between the physicians and labs HDL and/or Singulex; (4) P&H fees paid to the physicians; (5) waiver of copayments and deductibles for TRICARE beneficiaries; (6) testing services and test panels of the labs; (7) the process and handling work involved to prepare blood samples for shipment; (8) relationships and communications with the Defendants, entities owned or controlled by any defendant and sales representatives; (9) their intent to file, or cause or conspire with any Defendant to file, fraudulent claims to Medicare or TRICARE; (10) the impact, if any, of the Defendants' conduct on the medical judgment of the physician; (11) topics which the witnesses have information relevant to the allegations in the United States' Complaint in Intervention and defendants' Answers thereto; and, (12) topics which may be brought out in the Government's case-in-chief of which the witnesses have relevant information.

(Dkt. No. 763 at 2-3.)

II. Discussion

The Court has reconsidered its prior Order, specifically its finding about risk of prejudice to the Government that could result from allowing Defendants to call these physicians as trial witnesses. Although the Government had the opportunity to depose several of these treating physicians, the Court indicated in its prior Order that the Government would still be prejudiced because it did not have the opportunity to review an expert report and procure a rebuttal report. However, treating physicians are not necessarily required to provide an expert report under Rule 26 of the Federal Rules of Civil Procedure:

The requirement of a written report in paragraph (2)(B), however, applies only to those experts who are retained or specially employed to provide such testimony in the case or whose duties as an employee of a party regularly involve the giving of such testimony. A treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report. By local rule, order, or written stipulation, the requirement of a written report may be waived for

particular experts or imposed upon additional persons who will provide opinions under Rule 702.

Fed. R. Civ. P. 26, Notes of Advisory Committee on 1993 Amendment. Additionally, "A witness who is not required to provide a report under Rule 26(a)(2)(B) may both testify as a fact witness and also provide expert testimony under Evidence Rule 702, 703, or 705. Frequent examples include physicians or other health care professionals . . ." *Id.*, Notes of Advisory Committee on 2010 Amendment; *see also Drennen v. United States*, 375 F. App'x 299, 306 (4th Cir. 2010) (treating physician "was not retained or specially employed to provide expert testimony in this case" so did not need to produce an expert report).

The physicians in this case were not retained or specially employed to provide expert testimony, so they were exempt from having to produce an expert report for *some* testimony. "Numerous courts have held that a physician is exempt from this written report requirement only as to *opinions formed during the course of treatment.*" *Morris v. Bland*, 666 F. App'x 233, 239 (4th Cir. 2016) (emphasis added). The BlueWave Defendants were therefore not required to file an expert report disclosing the opinion of a treating physician that the physician formed during the course of treatment. Defendants were still obligated to identify such witnesses under Rule 26(a)(2)(A) and provide the disclosure required under Rule 26(a)(2)(C)¹ which provides that "Unless otherwise stipulated or ordered by the court, if the witness is not required to provide a written report, this disclosure must state: (i) the subject matter on which the witness is expected to present evidence under Federal Rule of Evidence 702, 703, or 705; and (ii) a summary of the

¹ The Rule 26(a)(2)(C) disclosure obligation does not include facts unrelated to the expert opinions the witness will present." Fed. R. Civ. P. 26, Notes of Advisory Committee on 2010 Amendment.

facts and opinions to which the witness is expected to testify." Defendants did not comply with the disclosure requirements of either Rule.

Under Rule 37(c)(l), "If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless." In evaluating whether nondisclosure was justified or harmless, the Court "should be guided by the following factors: (1) the surprise to the party against whom the evidence would be offered; (2) the ability of that party to cure the surprise; (3) the extent to which allowing the evidence would disrupt the trial; (4) the importance of the evidence; and (5) the non-disclosing party's explanation for its failure to disclose the evidence." Wilkins v. Montgomery, 751 F.3d 214, 221 (4th Cir. 2014) (quoting S. States Rack & Fixture v. Sherwin–Williams Co., 318 F.3d 592, 597 (4th Cir. 2003)) (emphasis omitted).

The Court has considered the *Southern States* factors and determined that (1) the physicians' testimony is important because the Government has alleged that Defendants orchestrated a scheme to pay kickbacks to these physicians to induce them to order medically unnecessary tests; (2) the Government is subject to some prejudice and surprise due to Defendants' failure to disclose the physicians in accordance with the rules, but that prejudice is mitigated by the fact that the Government had the opportunity to depose several of the physicians; and (3) allowing the physicians to testify about opinions they formed during the course of treatment will not disrupt the trial. Balancing these considerations, the Court finds that even though Defendants have provided no compelling justification for their failure to comply with the disclosure requirements under Rule(26), their failure is harmless under Rule 37(c)(1).

Defendants may call the physician witnesses to testify about any opinions they formed during the course of treatment.

The physician witnesses may also testify as fact witnesses² about relevant issues that fall within their own personal knowledge and experience. Such topics include but are not limited to several of those enumerated in Defendants' brief: "(1) background information on their medical practices, patient populations and their reasons for ordering lab tests; (2) BlueWave's sales and marketing practices; (3) process and handling (P&H) agreements between the physicians and labs HDL and/or Singulex; (4) P&H fees paid to the physicians; (5) waiver of copayments and deductibles for TRICARE beneficiaries; (6) testing services and test panels of the labs; (7) the process and handling work involved to prepare blood samples for shipment; (8) relationships and communications with the Defendants, entities owned or controlled by any defendant and sales representatives; (9) their intent to file, or cause or conspire with any Defendant to file, fraudulent claims to Medicare or TRICARE; (10) the impact, if any, of the Defendants' conduct on the medical judgment of the physician.³" ((Dkt. No. 763 at 2-3.)

The treating physicians may not, consistent with this Court's prior Order, testify as experts about any of these issues. The treating physicians may not rely on legal terms like "medical necessity" because they were not disclosed as experts and have not produced expert reports. The Court acknowledges that the physicians' testimony may unavoidably toe the line between permissible opinions formed during the course of treatment and impermissible expert

² The Government has not objected to the physicians testifying as fact witnesses. The parties did not previously brief the issue of the admissible scope of the physicians' testimony as fact witnesses.

³ The Court has not included Numbers 11 and 12 from Defendants list because they are catch-all descriptions of all relevant testimony.

opinion testimony. The Court will consider specific objections to the physicians' testimony at

trial.

III. Correction to Typographical Error in Prior Order

In preparing this Order, the Court identified a typographical error in its Order on the

Government's Motion in Limine. (Dkt. No. 736.) The final sentence of the section titled

"Settlement Amounts in Related Matters" reads: "Because the probative value of evidence about

settlement amounts outweighs the risk of unfair prejudice for any purpose Defendants have

disclosed that they intend to use it, the Government's motion to exclude this evidence is

granted." (Dkt. No. 736 at 9.) That sentence is hereby amended to read: "Because the risk of

prejudice inherent to evidence about settlement amounts in related matters outweighs the

probative value such evidence of for any purpose Defendants have disclosed that they intend to

use it, the Government's motion to exclude this evidence is granted."

IV. Conclusion

For the reasons set forth above, the Court has reconsidered its prior Order (Dkt. No. 736)

on the Government's Motion in Limine with respect to the testimony of treating physicians not

disclosed as experts. Those physicians may testify consistent with the findings in this Order.

AND IT IS SO ORDERED.

Richard Mark Gergel

United States District Court Judge

December 1, 2017

Charleston, South Carolina

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